

PATENT Customer No. 22,852

Attorney Docket No. 02481,1745-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

n re Application of:)
Evi KOSTENIS)) Group Art Unit: 1

Application No.: 09/899,295 Examiner: John Ulm

Filed: July 6, 2001

PROCESS FOR IDENTIFYING For: MODULATORS OF G-PROTEIN-

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Commissioner for Patents Washington, DC 20231

TECH CENTER 1600/2900

Sir:

RESPONSE TO OFFICE ACTION AND RESTRICTION REQUIREMENT

Applicant hereby responds to the Office Action of March 26, 2003. As April 26, 2003, falls on a Saturday, and this response is filed on or before Monday, April 28, 2003, Applicant submits that no extension of time fee is required to respond to this Office Action. Nevertheless, should the Office determine that a fee and/or extension of time is required to enter this response, Applicant requests that the Office grant the extension of time and charge any required fee to Deposit Account No. 06-0916.

Objections to Claims 57-170

Claims 1-170 are pending in this application. The Office objects to claims 57-112 as being allegedly of improper dependent form and objects to claims 113-170 as allegedly reciting an improper Markush group. (Office Action at page 2.) Applicant defers correction of these claims in light of Applicant's election to prosecute claims 1-56 in this application. (See below.)

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Restriction Requirement

The Office also requires restriction, under 35 U.S.C. § 121, to one of the following groups:

- I. Claims 1 to 56, classified in class 436, subclass 501;
- II. Claims 57 to 112, unclassified;
- III. Claims 113 to 158, and 168, SEQ ID NO:2, classified in class 435, subclass 69.1;
- IV. Claims 113 to 158, and 168, SEQ ID NO:4, classified in class 435, subclass 69.1;
- V. Claims 113 to 158, and 168, SEQ ID NO:6, classified in class 435, subclass 69.1;
- VI. Claims 113 to 158, and 168, SEQ ID NO:8, classified in class 435, subclass 69.1;
- VII. Claims 159 to 166, SEQ ID NO:2, classified in class 435, subclass 7.21;
- VIII. Claims 159 to 166, SEQ ID NO:4, classified in class 435, subclass 7.21;
- IX. Claims 159 to 166, SEQ ID NO:6, classified in class 435, subclass 7.21;
- X. Claims 159 to 166, SEQ ID NO:8, classified in class 435, subclass 7.21:
- XI. Claim 167, SEQ ID NO:2, classified in class 530, subclass 350;
- XII. Claim 167, SEQ ID NO:4, classified in class 530, subclass 350;
- XIII. Claim 167, SEQ ID NO:6, classified in class 530, subclass 350;
- XIV. Claim 167, SEQ ID NO:8, classified in class 530, subclass 350;
- XV. Claims 169 and 170, SEQ ID NO:2, classified in class 530, subclass 388.22;
- XVI. Claims 169 and 170, SEQ ID NO:4, classified in class 530, subclass 388.22;
- XVII. Claims 169 and 170, SEQ ID NO:6, classified in class 530, subclass 388.22; or,

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XVIII. Claims 169 and 170, SEQ ID NO:8, classified in class 530, subclass 388.22.

Applicant elects, with traverse, to prosecute Group I, claims 1-56.

Applicant traverses the Restriction Requirement for the following reasons.

Section 803 of the M.P.E.P. states that "[i]f the search and examination of the entire application can be made without serious burden, the examiner *must* examine it on the merits, even though it includes claims to independent or distinct inventions." M.P.E.P. § 803, emphasis added. Applicant respectfully submits that this policy should apply to this application in order to avoid unnecessary delay and duplicative examination.

Moreover, M.P.E.P. § 803.04 states that, while the Office considers nucleotide sequences encoding different proteins to be distinct, the Commissioner "has decided sua sponte to partially waive the requirements of 37 C.F.R. § 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application." Further, the M.P.E.P. states that "normally ten sequences constitute a reasonable number. *Id.*

Here, in contrast to the policy of M.P.E.P. § 803.04, the Office has required restriction of only four sequences, all of which encode G-proteins related in sequence and structure as described in Figure 1, page 9, ¶ 31, and pages 16-18, ¶¶ 58-62, of the specification. The Office has not explained why this application should not be accorded the treatment set forth in § 803.04. Moreover, the Office has placed each of SEQ ID NOS: 2, 4, 6, and 8 into a single class, as well as a single subclass, for searching purposes. Therefore, searching these four sequences in a single application presents no undue burden on the Office. Thus, Applicant urges the Office, at minimum, to follow

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the procedure of M.P.E.P. § 803.04 and collapse the sixteen groups III-VI, VII-X, XI-XIV, and XVI-XVIII into four groups. Indeed, examining sixteen separate applications would be much more of a burden and expense to the Office than examining four applications.

At the same time, each set of groups III-VI, VII-X, XI-XIV, and XVI-XVIII recites the same set of four sequences. Therefore, a search for the subject matter of each of those sets would be coextensive with a search for the subject matter of the others. For example, a search for the polynucleotide sequence of claim 113, Groups III-VI, should involve a search for the polypeptide of claim 167, Groups XI-XIV, that the polynucleotide may encode. A search for a host cell containing a particular polynucleotide is also coextensive with a search for that polynucleotide. (See Groups III-VI and VII-X.) In addition, claims 168, 169 and 170 all depend from claim 167, and so will be coextensive for searching purposes, yet the Office places them within separate groups. Therefore, placing claims 113-170 in a single group, or at least in four rather than sixteen groups, does not create any undue burden on the Office.

Finally, a search of the elected process of Group I, claims 1-56, would be coextensive with a search for the product of that process, claims 57-112, and would also be coextensive with a search of the polynucleotide sequences of SEQ ID NOS:2, 4, 6, and 8, because these sequences are recited in claims 1-56 as well as in claims 113-170.

Election of Species Requirement

Finally, the Office requires an election of species among each of following:

1. A host cell, for example, from among those listed in claim 14: HeLa, 293, COS, CHO, or *S. cerevisiae*.

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2. A combination of G-proteins, for example, from among those listed in claim 3: -6qi4myr, -6qs5myr, -6qi4, -6qs5, and G-α16.

3. A G-protein amino acid sequence, for example, from among SEQ ID NOS:2 (-6qi4myr), 4 (-6qs5myr), 6 (-6qi4), and 8 (-6qs5).

4. A G-protein-coupled receptor signal transduction pathway.

(Office Action at page 7.)

Applicant provisionally elects, with traverse, the following species from each of the above categories: CHO host cells, the combination of -6qi4myr and -6qs5myr, the amino acid sequence SEQ ID NO:2, and the PLC-β signal transduction pathway.

Applicant traverses the election requirement for the same reasons stated above with respect to the restriction requirement. It should not be an undue burden for the Office to search the subject matter of generic claim 1 over the limited number of G-protein combinations, host cells, amino acid sequences, and signal transduction pathways encompassed by the claimed invention. Pursuant to 37 C.F.R. § 1.146, should the Office find the elected species allowable, Applicant respectfully requests that the Office continue to examine the full scope of the subject matter to the extent necessary to determine its patentability, as is the duty according to 35 U.S.C. § 121.

Please grant any extensions of time required to enter this response and charge required fees not submitted herewith to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: April 28, 2003

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